REMARKS

Applicants have canceled Claims 1-89 without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or any other patent application. Applicants have now added NEW Claims 90-141. The amendments to the claims add no new matter and are fully supported by the specification as originally filed. In particular, support for the new claims can be found at, for example: page 3, line 17 and lines 27-31; page 4, lines 5-11 and lines 28-31; page 5, lines 9-16; page 13; page 14, lines 4-21; page 15; page 16, lines 25-31; page 17, lines 13-22; Example1 and Figure 1; Example 2 and Figure 2; and Example 3 and Figure 3; and elsewhere throughout the specification.

Applicants gratefully acknowledge the withdrawal of the provisional non-statutory double patenting rejection and the rejections under 35 U.S.C. § 103(a).

Interview Summary

Applicants thank the Examiner, Supervisory Examiner Campell, and QRS Examiner Eyler for meeting with Examiner's representative on January 29, 2007, to discuss the merits of the case and for the helpful comments made therein. Applicant's representative discussed the section 112 rejections and Applicants representative agreed to provide new claims that more clearly separate the invention from the daily administration of ribavirin and periodic (bi-weekly) administration of a hepatitis viral antigen, as taught by the prior art.

Informality

The Examiner has objected to the specification under 37 C.F.R. § 1.57(d) as allegedly containing a hyperlink. Applicants respectfully submit that they amended the specification to remove the hyperlink in the Amendment and Response to Office Action mailed May 22, 2006. *See,* Amendment and Response mailed May 22, 2006, page 2. Nevertheless, Applicants hereby request that the specification be amended to remove the hyperlink.

Rejection Under 35 U.S.C. § 112, first paragraph - Enablement

The Examiner has maintained the rejection of Claims 34-47, 51-55, 57-70, and 72-89 under 35 U.S.C. § 112, first paragraph, as allegedly not being described in the specification in such a way as to enable one skilled in the art to make and use the full scope of the claimed invention. According to the Examiner, the specification does not enable the induction of an immune response with "any or all antigen at any or [*sic*] concentration plus ribavirin at any concentration." *Office Action* at 3.

Although Applicants respectfully disagree with the Examiner's position, in an effort to expedite allowance of this application, the NEW claims now before the Examiner are based on the claim language found to be allowable in U.S. App. No. 10/817,591. Notably, the new claims are limited to methods of increasing the titer of hepatitis viral antigen specific IgG antibodies or producing a T cell response to a hepatitis viral antigen in a subject in need thereof "*consisting essentially of* providing, in a single administration, an immunogenic composition that comprises

an effective amount of ribavirin and said hepatitis viral antigen to said subject." As set forth in Section 2111.03 of the M.P.E.P., the transitional phrase "consisting essentially of" has a well-established meaning which occupies a middle ground between claims that recite the transitional phrase "consisting of," which exclude all steps (or materials) other than those recited in the claim, and claims that recite the transitional phrase "comprising," which do not exclude additional, unrecited steps (or materials). The transitional phrase "consisting essentially of" limits the scope of a claim by excluding additional materials or steps that materially affect the basic and novel characteristics of the invention. *Atlas Pander Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 224 (Fed. Cir. 1998).

Applicants maintain that in the instant case, the basic and novel characteristics of the NEW claims relate to increasing the production of hepatitis-specific IgG antibodies or producing a T cell response to a hepatitis viral antigen in a subject in need thereof by providing, *in a single administration, an immunogenic composition that comprises an effective amount of ribavirin and said hepatitis viral antigen.* Accordingly, any steps that materially affect the increase of the production of hepatitis-specific IgG antibodies or the production of a T cell response to hepatitis antigens in the identified subject or that are materially different than providing a single administration of an immunogenic composition that comprises an effective amount of ribavirin and a hepatitis viral antigen are excluded from the claims. As such, contrary to the Examiner's assertions, the claims do not encompass any concentration of ribavirin regardless of duration of the treatment." *Office Action* at 4. Accordingly, Applicants respectfully submit that the NEW claims traverse the rejections under 35 U.S.C. § 112 and request that these rejections be withdrawn.

Double Patenting

The Examiner has provisionally rejected Claims 34, 46, and 51 for statutory double patenting. Applicants have cancelled these claims and submit that the NEW claims comply with 35 U.S.C. § 101.

The Examiner has provisionally rejected several of the now cancelled claims for non-obviousness double patenting in light of U.S. App. Nos. 11/411,493 and 10/409,670. Applicants note that the Examiner has made a typographical error and that the correct application number should be 11/409,670. In an effort to expedite allowance of the present application, Applicants have filed herewith a Terminal disclaimer to overcome the provisional rejection based on U.S. App. Nos. 11/411,493 and 11/409,670. Applicants also note that the subject Terminal Disclaimer disclaims, with certain restriction, the terminal part of any patent granted on the present application, which would extend beyond the expiration date of the full statutory term of any patents that issue to U.S. Patent Application Serial Nos. 11/411,493, 11/409,670, 10/719,619, 11/411,318, and 11/411,494 and Applicants agree that any patent so granted on the present application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to a patent that issues to U.S. Patent Application Serial Nos. 11/411,493, 11/409,670, 10/719,619, 11/411,318, and 11/411,494.

CONCLUSION

The undersigned has made a good-faith effort to respond to the Office Action and to place the claims in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney, Eric S. Furman, Ph.D., at (619) 687-8643 (direct line) to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 13, 2007

By: _____

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